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14	UNITED STATES DIS	STRICT COURT		
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16	EASTERN DISTRICT	OF CALIFORNIA		
16				
17	VD VIII			
18	UNITED STATES,	CASE NO. 24 Misc.		
10	Petitioner,	PETITION OF THE UNITED STATES		
19		FOR ORDER TO SHOW CAUSE AND		
20	V.	SUMMARY ENFORCEMENT OF CIVIL INVESTIGATIVE DEMANDS 23-1300 TO		
	WOUND PROS MANAGEMENT GROUP, INC.;	23-1306 AND 23-1308 TO 23-1312		
21	WOUND PROS HOLDINGS, P.C.; WOUND			
22	PROS ENTERPRISES LLC; WOUND PROS TECHNOLOGY INC.; WOUND PROS			
	VENTURES, LP; WOUND PROS, P.C.; GLOBAL			
23	WOUND CARE MEDICAL GROUP; WOUND			
24	PROS TEXAS PLLC; WOUND PROS GEORGIA P.C.; WOUND PROS NEVADA INC.; WOUND			
	PROS DOCTORS P.C.; and WOUND PROS			
25	TENNESSEE, P.C.,			
26	Respondents.			
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This matter relates to an investigation by the United Sates under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq. Pursuant to 31 U.S.C. § 3733(j), the United States respectfully petitions this Court for an Order directing Respondents to comply with Civil Investigative Demands 23-1300 to 23-1306 and 23-1308 to 23-1312 ("the CIDs"), which were served on counsel for Respondents on September 29, 2023. As set forth further below, in the nearly nine months since service of the CIDs, Respondents have produced few of the documents that the CIDs require to be produced and have refused to identify or commit to a date by which they would produce key categories of documents. They have also only fully answered one of the twelve interrogatories.

In support of this Petition to enforce the CIDs, the United States provides the following:

### JURISDICTION AND VENUE

- 1. This Court has jurisdiction over this proceeding under 31 U.S.C. § 3733(j) and 28 U.S.C. § 1331.
  - 2. Venue is proper under 31 U.S.C. § 3733(j).

### **PARTIES**

- 3. Petitioner is the United States, filing this petition on behalf of the Department of Health and Human Services ("HHS"), Centers for Medicare and Medicaid Services ("CMS"); the Department of Defense ("DOD"); and the Department of Veterans Affairs ("VA"). CMS provides funding for the Medicare program, to pay for the costs of certain healthcare services, including physician services. DOD administers the TRICARE program, a health care program for active duty servicemembers. VA provides health care benefits to retired servicemembers.
- 4. Respondents are Wound Pros Management Group, Wound Pros Holdings, Wound Pros Enterprises, Wound Pros Technology, Wound Pros Ventures, Wound Pros PC, Global Wound Care Medical Group, Wound Pros Texas, Wound Pros Georgia, Wound Pros Nevada, Wound Pros Doctors,

Eastern District of California.

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### **ISSUANCE AND SERVICE OF THE CIDS**

and Wound Pros Tennessee. Each of the Respondents has billed Medicare for patient services within the

- 5. As described in the Memorandum accompanying this Petition, this investigation arises under the FCA, 31 U.S.C. §§ 3729 et seq. The FCA authorizes the United States to issue CIDs for the production of information relevant to FCA investigations.
- 6. On September 27, 2023, the CIDs were issued pursuant to the FCA by Jamie Ann Yavelberg, Director, U.S. Department of Justice, Civil Division, Commercial Litigation Branch, who is a designee of the Attorney General under 31 U.S.C. 3733(a)(1). See 28 C.F.R. Part 0, Subpt. Y App.
- 7. On September 29, 2023, the United States served the CIDs on Respondents by sending a copy to Respondents' then-counsel, Keith Greer. Since December 21, 2023, Respondents have been represented by current counsel, Hooper Lundy & Bookman.
- 8. The CIDs each seek production of documents responsive to twelve document requests and answers to twelve interrogatories.
- 9. As authorized by the FCA, the CIDs required each Respondent to produce responsive documents within 30 days of receiving the CIDs and to produce answers to the interrogatories within 20 days of receiving the CIDs. See 31 U.S.C. § 3733(a)(2)(E).
- 10. As stated in the CIDs, the United States is seeking such information and documents from Respondents in the course of an FCA investigation regarding whether Respondents and others:

made false statements in claims submitted to the federal healthcare programs in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, the Physician Self-Referral ("Stark") Law, 42 U.S.C. § 1395nn, and common law. Specifically, we are investigating whether Wound Pros submitted or caused the submission of (1) claims for reimbursement falsely stating that services provided by nonphysician personnel were "incident to" a physician's services; (2) claims for medically unnecessary skin substitutes and associated services; (3) point of service information falsely indicating that services were provided in an office setting; (4) claims for reimbursement through entities other than the one that performed the services; and (5) claims for durable medical equipment based on self-referrals in violation of the Stark Law.

reimbursable by the federal healthcare programs.

11. The United States issued the CIDs to Respondents because the United States has reason to

We further are investigating whether Wound Pros paid or caused the payment of unlawful kickbacks to personnel in exchange for the personnel ordering products and services

- believe that Respondents are in possession, custody, or control of documents and information relevant to this investigation.
- 12. The information and documents sought by the CIDs are reasonably relevant to the United States' investigation under the FCA inquiry, and the CIDs are not indefinite nor unduly burdensome.

# RESPONDENTS HAVE NOT PRODUCED ANY EMAILS OR SLACK DATA AND ARE UNWILLING TO PROVIDE PROJECTED PRODUCTION TIMELINES FOR SUCH

- 13. Nearly nine months after service of the CIDs, Respondents have produced few responsive documents.
- 14. Respondents have not produced any communications that are responsive to the CIDs. The CIDs require the production of communications relevant to each document request. Since November 2023, the United States has sought to coordinate with Respondents and repeatedly requested a plan for production of documents responsive to the CID, focusing on responsive communications. Consistently throughout discussions with counsel for Respondents, the United States has requested Respondents prioritize the production of relevant messages from two platforms the United States believes were used extensively in connection with the issues under investigation, email and Slack.
- Despite a lengthy back-and-forth with Respondents regarding their plan for reviewing email, Respondents have only just begun the actual review of emails for production and have been unable to provide a projected production timeline. On April 19, 2024, Respondents identified their plans to use Technical Assistance Review (TAR), which reviews documents with the assistance of artificial intelligence technology. Approximately one month later, on May 17, 2024, Respondents provided the United States a 3-page proposed TAR protocol, outlining certain general parameters for the identification of relevant emails. The proposed TAR protocol requires input from human reviewers to identify relevant

and non-relevant emails to "train" the technology. Despite this step, on May 28, 2024, Respondents

notified the government that they just began reviewing emails on June 21. Respondents remain unable to

estimate when they will produce any emails.

16. Similarly, Respondents have not produced any Slack data. Respondents have notified the government that they intend to produce all Slack channels that include the word "biologic" or "biologics." For the remaining Slack data, an additional review will be required, and Respondents have stated they are still deciding whether Slack messages will be included within their TAR protocol. While Respondents have projected that they will produce the "biologic" or "biologics" channels by the end of the month, they have provided no timeline for the remaining Slack data. Further they have been unable to provide a date by which they will decide whether they intend to include Slack data in the TAR protocol; a date by which

the Slack review will commence; or a projected timeline for producing the remaining Slack data.

- 17. Further, while the government has agreed to Respondents' plan to prioritize production of emails, Slack data, and interrogatory answers, Respondents have not outlined how they plan to identify other documents responsive to the CIDs, such as certain contracts and audits regarding the matters under investigation. Respondents have made certain limited productions of these materials but explained that they were not complete or comprehensive. Respondents have not (1) provided a plan for the review or production of these materials; (2) agreed to include them within TAR review; or (3) described how these documents are maintained by the Respondents. Further, we understand that Respondents' counsel remain unfamiliar with their clients' folder structures and document storage.
- 18. Not only have the CID recipients failed to produce these categories of documents, but, while negotiating productions, they have also repeatedly missed their own proposed deadlines or been unwilling to provide estimated deadline. And they have failed to begin work on the components of the production plan as discussed with the United States.

19. For instance, with respect to Respondents' email production, on January 17, 2024, Respondents notified the United States that they were on track to provide proposed search terms and hit counts by January 31, 2024. On January 31, 2024, Respondents did not provide such information. On February 1, 2024, the parties met and conferred on this topic. On February 16, 2024, over two weeks later, the entities provided proposed search terms, but the search terms were extremely limited and not appropriate for an investigation of this magnitude. The government sent additional search terms on March 7.

20. Respondents then notified the government that they may use TAR to review documents that hit on search terms. The government requested that Respondents confirm by March 29, 2024, whether they intend to use TAR and, if so, provide their proposed TAR protocol by April 9, 2024. Respondents agreed to let the government know whether they planned to use TAR by April 2, not March 29, and also agreed to share a proposed TAR protocol by April 9. Respondents did not confirm whether they intended to use TAR by April 2, nor did Respondents provide a TAR protocol. Respondents notified the government on April 18, two and half weeks after their proposed deadline of April 2, that they intend to use TAR. Respondents did not provide a proposed TAR protocol until May 17, 2024, over a month after the agreed-upon deadline of April 9.

21. The Respondents have provided five sets of interrogatory answers, dated November 10, 2023, December 4, 2023, April 1, 2024, May 31, 2024, and June 21, 2024. The first two interrogatory productions purported to answer all twelve interrogatories, but Respondents subsequently notified the government that all of the answers were incomplete and needed to be amended. On April 1, 2024, Respondents amended five of the interrogatories. Respondents subsequently notified the government that all but one of these answers required amendment. On May 31, 2024, Respondents provided four additional amended answers, but those answers raised concerns regarding completeness and clarity. The government responded with specific questions and comments regarding those answers on June 5, 2024, to which

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Respondents have not provided any responses. On June 21, 2024, Respondents answered one interrogatory but failed to include a certification of compliance. Despite five productions, Respondents have only fully addressed one interrogatory. Respondents have also missed several of their own proposed deadlines to answer interrogatories and, to date, have not provided a timeline for answering the remaining interrogatories.

### RESPONDENTS HAVE NOT FILED A PETITION TO MODIFY OR SET ASIDE THE CIDS

- 22. The CIDs directed Respondents to produce all documents by October 30, 2023, thirty days after service of the Demands. The CIDs directed Respondents to answer the interrogatories by October 19, 2023, 20 days from receipt of the Demand.
- 23. Under the FCA, 31 U.S.C. § 3733(j)(2)(A)(i), the deadline for Respondents to petition to modify or set aside CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312 was no later than October 30, 2023.
  - 24. To date, Respondents have not petitioned to modify or set aside the CIDs.
- 25. It has been over 270 days since Respondents received service of the CIDs. Yet Respondents have produced no emails or Slack data and only a small portion of the other documents subject to the CIDs (around 5,600 documents in total, which the Respondents have identified as incomplete representations of the document categories required by the CID). Further, Respondents have refused to provide any deadlines by which they will fully respond to the CIDs. Respondents have also only fully answered one of the twelve interrogatories.
  - 26. Accordingly, summary enforcement of the CIDs is appropriate.

WHEREFORE, the United States respectfully request as follows:

1. That this Court enter an Order to Show Cause directing Respondents to show cause as to why they should not be compelled to comply with CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312; and

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1	2. Ultimately, that this Court enter an Order directing Respondents to comply with CIDs 23.			
2	1300 to 23-1306 and 23-1308 to 23-1312 on or before the deadlines proposed by the United States or such			
3	other deadlines set by the Court.			
4	DATED: June 27, 2024	Respectfully submitted,		
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6		Principal Assistant Attorney General		
7 8		PHILLIP A. TALBERT United States Attorney		
9 10		JAMIE ANN YAVELBERG ANDY MAO		
11	Ву	: <u>/s/ Laura Hill</u> LAURA HILL		
12		Trial Attorney		
13		DAVID E. THIESS Assistant United States Attorney		
14		Assistant Office States Attorney		
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15	UNITED STATES DISTRICT COURT			
16	EASTERN DISTRICT OF CALIFORNIA			
17				
18	UNITED STATES,	CASE NO. 24 Misc		
19	Petitioner,	MEMORANDUM IN SUPPORT OF THE UNITED STATES' PETITION FOR AN		
20	V.	ORDER TO SHOW CAUSE AND SUMMARY ENFORCEMENT OF CIVIL		
21	WOUND PROS MANAGEMENT GROUP, INC.; WOUND PROS HOLDINGS, P.C.; WOUND	INVESTIGATIVE DEMANDS 23-1300 TO 23-1306 AND 23-1308 TO 23-1312		
22	PROS ENTERPRISES LLC; WOUND PROS TECHNOLOGY INC.; WOUND PROS			
23	VENTURES, LP; WOUND PROS, P.C.; GLOBAL WOUND CARE MEDICAL GROUP; WOUND			
24	PROS TEXAS PLLC; WOUND PROS GEORGIA P.C.; WOUND PROS NEVADA INC.; WOUND			
25	PROS DOCTORS P.C.; and WOUND PROS TENNESSEE, P.C.,			
26	Respondents.			
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By its petition, the United States of America seeks to enforce provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., that authorize the United States to obtain "documentary material" and answers to "written interrogatories" that are "relevant to a false claims law investigation" through the issuance of Civil Investigative Demands ("CIDs"). 31 U.S.C. § 3733(a)(1). Such material may be obtained where, as here, the United States has not "commenc[ed] a civil proceeding" or "ma[de] an election" under the FCA. *Id*.

Given the importance of the information sought to the United States' investigation, the United States has communicated regularly with Respondents regarding the CIDs at issue, CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312 ("the CIDs"); however, those communications have not borne fruit.

Despite the United States' attempts to accommodate Respondents (such as prioritizing certain requests), Respondents have produced very few documents since service of the CIDs in September of last year and have failed even to provide production timelines for the communications and other documents sought by the CIDs. As such, the United States respectfully requests the Court order the Respondents to show cause as to why they should not be compelled to comply with the CIDs and, ultimately, requests the Court enforce the CIDs.

### **BACKGROUND**

Wound Pros Management Group, Inc.; Wound Pros Holdings, P.C.; Wound Pros Enterprises LLC; Wound Pros Technology Inc.; Wound Pros Ventures, LP; Wound Pros, P.C.; Global Wound Care Medical Group; Wound Pros Texas PLLC; Wound Pros Georgia, P.C.; Wound Pros Nevada, Inc.; Wound Pros Doctors, P.C.; and Wound Pros Tennessee, P.C. ("Respondents") provide medical wound treatment and/or durable medical equipment to patients. The United States is investigating whether Respondents and others made false statements in claims submitted to the federal healthcare programs in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, the Physician Self-Referral ("Stark") Law, 42 U.S.C. § 1395nn, and common law. Specifically, the United States is investigating whether Wound Pros submitted or caused the submission of (1) claims for reimbursement falsely stating that services provided by non-physician personnel were "incident to" a physician's services; (2) claims for medically unnecessary skin substitutes and associated services; (3) point of service information falsely indicating that services were provided in an office

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setting; (4) claims for reimbursement through entities other than the one that performed the services; and (5) claims for durable medical equipment based on self-referrals in violation of the Stark Law. The United States is also investigating whether Respondents paid or caused the payment of unlawful kickbacks to personnel in exchange for their ordering products and services reimbursable by the federal healthcare programs. Specifically, the government is investigating whether Respondents paid all clinicians, including 1099 contractors, a bonus every time the clinicians used a skin substitute in violation of the Anti-Kickback Statute.

As part of the investigation, on September 27, 2023, the CIDs were issued pursuant to the FCA by Jamie Ann Yavelberg, Director, U.S. Department of Justice, Civil Division, Commercial Litigation Branch, who is a designee of the Attorney General under 31 U.S.C. § 3733(a)(1). See Declaration of Laura Hill ("Decl."), Exs. 1-12 (CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312). The CIDs each seek documents responsive to twelve document requests and answers to twelve interrogatories, id., and were served on counsel for the Respondents on September 29, 2023, Decl. Ex. 13. The United States is seeking such information and documents from Respondents in the course of an FCA investigation.

In response to the CIDs, served nearly nine months ago, the Respondents have produced very few documents, a number of which are unresponsive to the CIDs' document requests. Of particular note, the Respondents have failed to produce any emails or Slack data, the two categories of documents the government has requested Respondents prioritize. Further, Respondents have only fully answered one of the twelve interrogatories.

Emails. Respondents have not yet produced a single email. The CIDs were served on counsel for Respondents in September 2023. Decl., Ex. 13. Respondents did not produce any emails under original counsel. Respondents' changed counsel in December 2023. On December 21, 2023, during the government's first call with Respondents' current counsel, the government focused on email production, requesting that Respondents provide search terms and prepare "hit" counts, showing the number of emails containing those search terms by January 31, 2024. Decl., Ex. 14. The government also agreed to Respondents' plan to prioritize productions for certain custodians. *Id.*; see also Decl., Ex. 16. On January 17, 2024, Respondents notified the United States that they were on track to provide proposed search terms and hit counts by January 31, 2024. Decl., Ex. 15. On January 31, 2024, Respondents did

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not provide such information. *See* Decl., Ex. 16 (requesting Respondents propose a deadline for providing the proposed search terms and hit counts). On February 1, 2024, the parties met and conferred on this topic. *See id*. On February 16, 2024, over two weeks later, Respondents provided proposed search terms, but the search terms were limited and not appropriate for an investigation of this magnitude. *See* Decl., Ex. 17 (Respondents' Fourth Production Letter). After the government sent additional search terms for consideration, Respondents notified the government that they may use Technology Assisted Review (TAR) to review documents that hit on search terms.

After this notification, the government requested that Respondents confirm by March 29, 2024,

whether they intended to use TAR and, if so, to provide their proposed TAR protocol by April 9, 2024. Decl., Ex. 18. In response, Respondents stated they would let the government know whether they planned to use TAR by April 2, not March 29. Decl., Ex. 19. They also agreed to share a proposed TAR protocol by April 9. *Id.* On April 2, 2024, the Respondents failed to confirm whether they intended to use TAR as they had agreed, and Respondents did not provide a TAR protocol. Decl., Ex. 20. Respondents notified the government on April 18, two and half weeks after their proposed deadline of April 2, of their intent to use TAR. Decl., Ex. 21. Respondents did not provide a proposed TAR protocol until May 17, 2024, over a month after the agreed-upon deadline of April 9. *See* Decl., Exs. 26, 26-1 (Respondents' TAR protocol). Respondents notified the government that on June 21, almost nine months after service of the CIDs, they had only just begun reviewing emails for production. Decl., Ex. 35. Respondents further notified the government that they were unable to provide a projected production timeline. *Id*.

Slack data. Slack is a cloud-based team communication platform. Similar to emails subject to the CIDs, on December 21, 2023, during the government's first call with the Respondents' current counsel, the government requested the Respondents promptly begin collecting Slack content associated with an agreed-upon list of priority custodians. Decl., Ex. 14. Since that time, Respondents have been unable to report to the government whether they intend to use TAR to review the data, and, despite repeated requests, they have failed to provide a projected production timeline for responsive Slack data. Decl., Ex. 22, 25, 27, 34, 35.

Since the initial call with current counsel on December 21, 2023, the government has repeatedly requested updates from the Respondents on Slack data. On April 18, 2024, the Respondents stated they would provide a proposed process for reviewing Slack messages by May 2, 2024. Decl., Ex. 21. On May 2, 2024, the government received no update from the Respondents. *See* Decl., Ex. 22. On May 3, 2024, the government again requested the Respondents share their proposed process for reviewing Slack messages. *Id.* On May 9, 2024, the Respondents provided their proposed approach for reviewing Slack messages. Decl., Ex. 23. Respondents intend to produce all Slack channels containing the words "biologic" or "biologics." *Id.* According to Respondents, they expect to be able to produce these channels by the end of June. Decl., Ex. 35. For the remaining Slack data, Respondents proposed a custodial approach that prioritizes 9 custodians, similar to their email review. *Id.* After the government requested a proposed production timeline, the Respondents stated, on May 14, 2024, they would be able to provide a projected timeline "in the next few weeks." Decl., Exs. 24, 25. On May 31, 2024, the Respondents backtracked, stating they were unable to even provide a timeline for proposing a production timeline. Decl., Ex. 27. As of the date of filing, Respondents have yet to provide a projected production timeline. See Decl., Exs. 27, 34, 35.

Interrogatories. The Respondents have provided five sets of interrogatory answers, dated November 10, 2023, December 4, 2023, April 1, 2024, May 31, 2024, and June 21, 2024. Decl., Exs. 28, 29, 30, 31, 32. The first two interrogatory productions purported to answer all twelve interrogatories, Decl., Ex. 28, 29, but Respondents subsequently notified the government that all of the answers were incomplete and needed to be amended. On April 1, 2024, Respondents amended five of the interrogatories. Decl. Ex. 30. Respondents subsequently notified the government that all but one of these answers required amendment. On May 31, 2024, Respondents provided five amended answers, but the government continues to have significant questions regarding the completeness and accuracy of these answers, which Respondents have not addressed. Decl. Ex. 33. Respondents have notified the government that they intend to produce a complete answer to Interrogatory 4 on June 28. Decl., Ex. 35. Respondents provided a response to Interrogatory 8 on June 21, 2024, but failed to include the required

certification of compliance. Decl., Ex. 32. Respondents have failed to provide a timeline for answering the remaining interrogatories. *See* Decl., Ex. 35.

### **LEGAL STANDARD FOR ENFORCEMENT**

The FCA "is the government's primary litigative tool for combatting fraud against the federal government." *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (internal quotation marks omitted); *Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989). Under the FCA, a CID may be issued to "any person" the United States "has reason to believe . . . may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation." 31 U.S.C. § 3733(a)(1). The FCA empowers the United States to issue such CID "before commencing a civil proceeding under [FCA] section 3730(a) or other false claims law, or making an election under [FCA] section 3730(b)." *Id.* By enacting the statutory authority for CIDs under the FCA, Congress sought to enable the United States "to determine whether enough evidence exist[s] to warrant the expense of filing [a civil] suit, as well as to prevent the potential Defendant from being dragged into court unnecessarily." *United States v. Witmer*, 835 F. Supp. 208, 211 (M.D. Pa. 1993) (quoting H.R. Rep. 660, 99th Cong., 2d Sess. 26 (1986)).

A CID under the FCA is a type of administrative subpoena, and the standard for enforcing an administrative subpoena applies to a petition to enforce a CID. *See United States v. Markwood*, 48 F.3d 969, 976 (6th Cir. 1995); *accord United States v. ASG Solutions Corp.*, No. 17-cv-1224, 2018 WL 1418023, at \*3 (S.D. Cal. Mar. 22, 2018), *adopted by*, 2018 WL 3471405 (S.D. Cal. July 18, 2018). While the United States' "authority to request records and undertake other investigatory functions is extremely broad," *Santa Fe Energy Prods. Co. v. McCutcheon*, 90 F.3d 409, 414 (10th Cir. 1996) (citing *United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950)), a court's "role in [reviewing] the enforcement of an administrative subpoena is a limited one." *Markwood*, 48 F.3d at 975–76; *EEOC v. Golden Valley Elec. Ass'n*, 689 F.3d 1108, 1113 (9th Cir. 2012) ("The scope of judicial review in an administrative subpoena enforcement proceeding is 'quite narrow.""); *see also FTC v. Texaco, Inc.*, 555 F.2d 862, 871–72 (D.C. Cir. 1977), *cert. denied*, 431 U.S. 974 (1977) (scope of judicial review on request for enforcement of administrative subpoena is "strictly limited").

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Enforcement of an administrative subpoena, such as a CID issued pursuant to the FCA, is proper as long as the Court finds that: (1) "Congress has granted authority to investigate," (2) "procedural requirements have been followed," and (3) "the evidence is relevant and material to the investigation." *E.E.O.C. v. Fed. Express Corp.*, 558 F.3d 842, 848 (9th Cir. 2009) (quoting *E.E.O.C. v. Karuk Tribe House Auth.* 260 F.3d 1071, 1076 (9th Cir. 2001)); see Morton Salt, 338 U.S. at 642–43 (administrative order issued by FTC); Witmer, 835 F. Supp. at 220–21 (adopting Morton Salt standard for enforcing CID under FCA); see also United States v. Picetti, No. 19-49, 2019 WL 1895057, at \*2 (E.D. Cal. April 29, 2019) (enforcing CID using this standard). Once the United States has demonstrated the above factors, the CID should be enforced unless the CID recipient demonstrates that the CID is overbroad or unduly burdensome. Picetti, 2019 WL 1895057, at \*2; see also EEOC v. Kloster Cruise Ltd., 939 F.2d 920, 922 (11th Cir. 1991).

### **ARGUMENT**

- I. Enforcement of CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312 Is Appropriate.
  - A. The CIDs Are Within the Jurisdiction Provided by the FCA, and All Procedural Requirements Have Been Followed.

The CIDs fall squarely within the authority provided by the FCA. The FCA provides civil remedies to the Government against "all fraudulent attempts to cause the Government to pay out sums of money." *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968). Here, and as described in more detail above, the government is investigating allegations that the defendants caused the submission of claims with false information about how services were performed and/or that did not comply with the requirements for payment under various federal health care programs.

When enacting the FCA authority for CIDs, Congress recognized that "[f]raud actions, by nature, are difficult to piece together," and "[c]ircumstantial evidence" is "generally necessary in determining whether fraud has been committed." H.R. Rep. 660, 99th Cong., 2d Sess. 26 (1986). The FCA expressly allows the United States to issue CIDs to investigate potential FCA violations. 31 U.S.C. § 3733(a)(1); accord ASG Solutions, 2018 WL 1418023, at \*4.

The CIDs also comply with all procedural requirements set forth in the FCA. The government properly served Respondents' counsel, Decl., Ex. 13, and complied with the contents and deadlines

requirement set forth in 31 U.S.C. §§ 3733(a)(2)(B), (C), and (E), Decl., Exs. 1-12. For the document requests, the CIDs described each class of documentary material to be produced with definitiveness and certainty, prescribed a reasonable return date, and identified the false claims law investigators. Decl., Exs. 1-12; 31 U.S.C. §§ 3733(a)(2)(B). For the interrogatories in the CIDs, the demands set forth the interrogatories with specificity, prescribed reasonable dates for a return, and identified the false claims law investigators. Decl., Exs. 1-12; 31 U.S.C. §§ 3733(a)(2)(C). As such, the CIDs were properly issued.

# B. The Documents and Interrogatory Answers Sought by the CIDs Are Relevant to the Matters Under Investigation.

"Relevancy is determined in terms of the investigation rather than in terms of evidentiary relevance." *Golden Valley*, 689 F.3d at 1113. Relevance is broadly construed when enforcing administrative subpoenas, *see Texaco*, 555 F.2d at 872, and "[t]he relevance requirement is 'not especially constraining." *Golden Valley*, 689 F.3d at 1113 (quoting *Fed. Exp. Corp.*, 558 F.3d at 854; *see also United States v. Joint Active Systems, Inc.*, 2020 WL 9747630, at \*4 (D. Mass. May 20, 2020) (quoting *ASG Solutions Corp.*, 2018 WL 1418023, at \*5). "[C]ourts must enforce administrative subpoenas unless the evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose of the agency." *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076 (9th Cir. 2001) (internal quotation marks omitted).

The CIDs seek documents and interrogatory answers that will allow the United States to evaluate whether the Respondents submitted, or caused the submission, of false claims. *See* 31 U.S.C. § 3729(a)(1); Decl., Exs. 1-12. Among other items, the CIDs seek documents and interrogatory answers regarding the Respondents' affiliations and corporate structure, which relates to all areas of the investigation but especially the Stark Law allegations and allegations regarding Respondents submitting claims for reimbursement through entities other than the one that performed the services; documentation regarding salaries, commissions, bonuses, and other remuneration, which is especially significant for the investigation of unlawful kickbacks; and documents and communications regarding physician supervision, directly related to the government's investigation of whether Respondents submitted claims for reimbursement that falsely stated that services provided by non-physician personnel were directly

supervised by physicians, as required to bill certain federal health care programs for those services at a

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higher payment rate, as "incident to" a physician's services. *Id*. The CIDs' requests are directly relevant to the government's investigation.

### C. The CIDs Are Not Indefinite or Unduly Burdensome.

Respondents, as the CID recipients, bear the burden to show that the CIDs are indefinite or unduly burdensome. See Golden Valley, 689 F.3d at 1115; Texaco, 555 F.2d at 882. Where the investigation "is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met." SEC v. Brigadoon Scotch Distrib. Co., 480 F.2d 1047, 1056 (2d Cir. 1973).

Respondents have not provided a justification for their delay. They have lodged several boilerplate objections to the document requests which do not justify or speak to the delay. Among other objections, Respondents allege the government seeks (1) irrelevant information, (2) documents that may be confidential, proprietary, or privileged, (3) cumulative evidence, and (4) information outside the FCA statute of limitations or in the public domain. Contrary to the recipients' objections, the government is not seeking privileged documents or documents outside of the statute of limitations. Dec., Ex. 27, 28, 29, 30. And relevancy is defined broadly in the CID context. See Joint Active Systems, Inc., 2020 WL 9747630, at \*4. "Courts 'must enforce administrative subpoenas unless the evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose of the agency." Id. The government's document requests are plainly relevant to the FCA investigation.

The CIDs are also not unduly burdensome. The United States is investigating Respondents' conduct; they are not third parties to the investigation. And "[s]ome burden on subpoenaed parties is to be expected and is necessary in furtherance of the [United States'] legitimate inquiry and the public interest," Texaco, 555 F.2d at 882. Although everything the government requested was relevant to its investigation, the United States agreed to Respondents' request to prioritize certain categories of documents for production; agreed to Respondents' plan of applying search terms to documents, see, e.g., Decl., Exs. 14-18 (discussing search terms); worked with Respondents on a TAR protocol to apply after application of search terms, Decl., Exs. 26, 26-1; and agreed to prioritize the production of documents associated with certain custodians, Decl., Ex. 14, 16. Despite continuous efforts by the United States to coordinate with Respondents on a reasonable review protocol and document production schedule,

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Respondents have produced very little in the almost nine-month period since service of the CIDs. Also, Respondents have been unable or unwilling to even provide a production schedule for any category of documents requested by the CIDs, let alone a production schedule for completing productions under the CIDs.

D. Wound Pros Entities Waived Objection to CIDs 23-1300 to 23-1306 and 23-1308 to 23-1312.

Pursuant to the FCA, Respondents were required to timely respond to the CIDs by either producing the information sought, 31 U.S.C. §§ 3733(f)(1)-(2), (g)(1), or by timely petitioning the court to modify or set aside the CID, *id.* § 3733(j)(2)(A)(i). Respondents failed to do either, thus waiving any arguments they could have raised to modify or set aside the CIDs.

It has been over 270 days since Respondents received service of the CIDs. The United States has endeavored to work in good faith with the Respondents, but that approach has not worked. The United States has an "important governmental interest in the expeditious investigation of possible unlawful activity," *Markwood*, 48 F.3d at 979. Respondents are not entitled to delay the United States' investigation by refusing to comply with valid CIDs.

### **CONCLUSION**

For the above reasons, the United States respectfully requests that the Court grant its petition and order Respondents to show cause and, ultimately, comply with CIDs 23-1300 to 23-1306 and 23-1308 to

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# Case 24-34908 Document 17-1 Filed in TXSB on 10/24/24 Page 19 of 60 Case 2:24-mc-00263-DJC-AC Document 1-1 Filed 06/27/24 Page 11 of 11

1	23-1312 on or before the deadlines proposed by the United States, or such other deadlines set by the			
2	Court.			
3	DATED: June 27, 2024	Respectfully submitted,		
4		BRIAN M. BOYNTON		
5		Principal Assistant Attorney General		
6		PHILLIP A. TALBERT United States Attorney		
7		JAMIE A. YAVELBERG		
8		ANDY MAO		
9	By:			
10		LAURA HILL Trial Attorney		
11		DAVID E. THIESS		
12 13		Assistant United States Attorney		
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7	JAMIE A. YAVELBERG ANDY MAO		
8	LAURA E. HILL Department of Justice		
9	Civil Division Commercial Litigation Branch		
10	175 N Street, NE, 9th Floor Washington, DC 20002		
11	Telephone: (202) 514-7900 <u>Laura.E.Hill@usdoj.gov</u>		
12 13	Attorneys for the United States		
14			
15	UNITED STATES DISTRICT COURT		
16	EASTERN DISTRICT OF CALIFORNIA		
17			
18	UNITED STATES,	CASE NO. 24 Misc	
19	Petitioner,	DECLARATION OF COUNSEL IN SUPPORT OF THE UNITED STATES'	
20	v.	PETITION FOR ORDER TO SHOW CAUSE AND SUMMARY	
21	WOUND PROS MANAGEMENT GROUP, INC.; WOUND PROS HOLDINGS, P.C.; WOUND	ENFORCEMENT OF CIVIL INVESTIGATIVE DEMANDS 23-1300 TO	
22	PROS ENTERPRISES LLC; WOUND PROS TECHNOLOGY INC.; WOUND PROS	23-1306 AND 23-1308 TO 23-1312	
23	VENTURES, LP; WOUND PROS, P.C.; GLOBAL WOUND CARE MEDICAL GROUP; WOUND		
24	PROS TEXAS PLLC; WOUND PROS GEORGIA P.C.; WOUND PROS NEVADA INC.; WOUND		
25	PROS DOCTORS P.C.; and WOUND PROS TENNESSEE, P.C.,		
26	Respondents.		
27	I I over E Hill doctors and state as full		
28	I, Laura E. Hill, declare and state as follows:		

- 1. I am a Trial Attorney in the U.S. Department of Justice, Civil Division, and have been assigned to work on this matter. I make this declaration in support of the United States' petition to enforce compliance with Civil Investigative Demands 23-1300 to 23-1306 and 23-1308 to 23-1312 ("the CIDs") issued to Wound Pros Management Group, Wound Pros Holdings, Wound Pros Enterprises, Wound Pros Technology, Wound Pros Ventures, Wound Pros PC, Global Wound Care Medical Group, Wound Pros Texas, Wound Pros Georgia, Wound Pros Nevada, Wound Pros Doctors; and Wound Pros Tennessee ("Respondents").
  - 2. Attached hereto as Exhibits 1-12 are true and correct copy of the CIDs.
- 3. Attached hereto as Exhibit 13 is a true and correct copy of a September 29, 2023, email serving the CIDs on Respondents' counsel.
- 4. Attached hereto as Exhibit 14 is a true and correct copy of government counsel's December 21, 2023, email to Respondents' counsel, memorializing a December 21, 2023, call. The email reiterates that the government requested Respondents provide search terms and prepare hit counts by January 31, 2024; discussed Respondents proposed custodians; and requested Respondents promptly begin collecting Slack content for an agreed-upon list of priority custodians.
- 5. Attached hereto as Exhibit 15 is government counsel's January 17, 2024, email memorializing a call on the same day with Respondents' counsel during which Respondents noted they were on track to provide proposed search terms and hit counts by January 31, 2024.
- 6. Attached hereto as Exhibit 16 is government counsel's February 2, 2024, email memorializing a call on February 1, 2024. The email notes, "We understand that you plan to use search terms in connection with your review of the custodial emails, and you agreed to provide proposed search terms and hit counts for our consideration." The email also requested Respondents propose a deadline by which the proposed search terms and hit counts would be provided.

- 7. Attached hereto as Exhibit 17 is Respondents' Fourth Production Letter, dated February 16, 2024, which includes Respondents' proposed search terms.
- 8. Attached hereto as Exhibit 18 is government counsel's March 25, 2024, email, memorializing a March 21, 2024, call. The email notes that Respondents agreed to let government counsel know by March 29 whether they intended to use technology-assisted review ("TAR") to review the documents that hit on the search terms. The email also provides an April 9 deadline to share a proposed TAR protocol.
- 9. Attached hereto as Exhibit 19 is Respondents' March 25, 2024, email, noting that Respondents will notify the government whether they plan to use TAR by April 2 and that they would circulate a proposed TAR protocol by April 9.
- 10. Attached hereto as Exhibit 20 is Respondents' April 2, 2024, email, stating, "We are still in the process of determining whether TAR would be a viable method to review the emails."
- 11. Attached hereto as Exhibit 21 is government counsel's April 19, 2024, email memorializing a call with Respondents on April 18, 2024. The email notes that Respondents confirmed on April 18 their intent to use TAR and that they would provide a proposed process for reviewing Slack messages by May 2, 2024.
- 12. Attached hereto as Exhibit 22 is government counsel's May 3, 2024, email requesting Respondents provide a deadline for sharing a draft of the TAR protocol and requesting Respondents share their proposed process for reviewing Slack messages.
- 13. Attached hereto as Exhibit 23 is Respondents' May 9, 2024, email outlining their proposed approach for reviewing Slack messages and noting they were unable to provide a "firm date for circulation of our proposed TAR protocol" but would provide a status update by May 14, 2024, if they had not finalized the protocol before that date.

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14. Attached hereto as Exhibit 24 is government counsel's May 9, 2024, email requesting a proposed production timeline for the Respondents' Slack messages and interrogatory answers.

- 15. Attached hereto as Exhibit 25 is Respondents' May 14, 2024, email, stating that they would be able to provide a projected timeline on Slack productions "in the next few weeks." The email also fails to include a projected timeline for answering interrogatories, stating, "we are continuing to work with our client on verifications and amended interrogatory responses and expect to provide another update by this Friday, May 17, 2024."
- 16. Attached hereto as Exhibits 26 and 26-1 are Respondents' May 17, 2024, email, providing a proposed TAR protocol and the proposed TAR protocol, respectively.
- 17. Attached hereto as Exhibit 27 is government counsel's May 31, 2024, email, memorializing two earlier calls—on May 24 and 28—with Respondents. The email notes that Respondents notified the government that, as of May 28, 2024, they have not begun reviewing emails for production. The email further memorializes that Respondents notified the government that they were unable to provide an estimate for when they would begin reviewing emails and were unable to provide a projected production timeline. The email also confirms that the Respondents had not begun the process to expand the Slack data; had not begun reviewing any Slack data for production; were unable to report to the government whether they intended to use TAR to review the data; and were unable to provide a projected production timeline for responsive Slack data.
- 18. Attached hereto as Exhibits 28 (November 10, 2023, Response to Interrogatories 1-12), 29 (December 5, 2023, Respondents' First Amended Response to Interrogatories), 30 (April 1, 2024, Respondents' Second Amended Response to Interrogatories), 31 (May 31, 2024, Respondents' Third Amended Response to Interrogatories), and 32 (June 21, 2024, Respondents' Fourth Amended Response to Interrogatories) are Respondents' interrogatory answers. The Answers include Respondents' objections to the Interrogatories.

- 19. Attached hereto as Exhibit 33 is government's counsel June 5, 2024, email providing clarifications as requested to Respondents' May 31, 2024, interrogatory answers. The email also seeks clarification as to the interrogatory answers.
- 20. Attached hereto as Exhibit 34 is government counsel's June 17, 2024, email to Respondents' counsel, memorializing a June 14, 2024, call. The email notes that, by June 21, 2024, Respondents agreed to provide an email production deadline and a deadline for producing answers to the remaining interrogatories. The email also states that Respondents intend to produce the "biologics' channels"—Slack channels that hit on the terms "biologics" or "biologic"—by the end of the month yet are unable to provide a projected production timeline for the remaining Slack data.
- 21. Attached hereto as Exhibit 35 is Respondents' counsel's June 21, 2024, reply, noting, among other things, that Respondents expect to produce Slack channels that hit on "biologics" by the end of the month; failing to provide an email production deadline; and failing to provide a projected timeline for answering all remaining interrogatories.

DATED: June 27, 2024 Respectfully submitted,

/s/ Laura Hill
LAURA HILL
Trial Attorney

# Exhibit 7

### **CIVIL INVESTIGATIVE DEMAND**

### United States Department of Justice

Washington, D.C. 20530

TO: Global Wound Care Medical Group 5901 W. Century Blvd, Suite 750 Los Angeles, California 90045 c/o Curtis Keith Greer (Registered Agent) 16855 W Bernardo Drive, Suite 255 San Diego, California 92127 Civil Investigative Demand No. 23-1306

This Civil Investigative Demand is issued pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, in the course of a False Claims Act investigation to determine whether there is or has been a violation of 31 U.S.C. § 3729. The False Claims Act investigation concerns allegations that Wound Pros, P.C. f/k/a Wound Pros LLC, Global Wound Care Medical Group, Ohio Wound Care Physicians Inc., Wound Care Medical Group P.C., Wound Pros Arizona, P.C., Wound Pros Doctors P.C., Wound Pros Florida, P.A. f/k/a Wound Pros Florida, Inc., Wound Pros Georgia P.C. f/k/a Wound Pros Georgia Inc., Wound Pros Michigan, P.C. f/k/a Wound Pros Michigan Inc., Wound Pros Nevada Inc., Wound Pros New York Inc., Wound Pros Ohio Inc., Wound Pros Tennessee, P.C. f/k/a Wound Pros Tennessee Inc., Wound Pros Texas PLLC f/k/a Wound Pros Texas Inc., WP Texas Medical Group P.C., Washington Wound Pros Nevada, P.C., Wound Pros Holdings, P.C., Wound Pros Enterprises LLC, Wound Pros Technology Inc., Wound Pros Ventures, LP, Wound Pros Management Group, Inc., and certain related entities and individuals (collectively, "Wound Pros") made false statements in claims submitted to the federal healthcare programs in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, the Physician Self-Referral ("Stark") Law, 42 U.S.C. § 1395nn, and common law. Specifically, we are investigating whether Wound Pros submitted or caused the submission of (1) claims for reimbursement falsely stating that services provided by non-physician personnel were "incident to" a physician's services; (2) claims for medically unnecessary skin substitutes and associated services; (3) point of service information falsely indicating that services were provided in an office setting; (4) claims for reimbursement through entities other than the one that performed the services; and (5) claims for durable medical equipment based on self-referrals in violation of the Stark Law. We further are investigating whether Wound Pros paid or caused the payment of unlawful kickbacks to personnel in exchange for the personnel ordering products and services reimbursable by the federal healthcare programs.

This Demand requires you to provide documents and answers to the attached written interrogatories to the Federal Government. This is the original of the Demand; no copies have been served on other parties. The information and documents provided in response to this Demand may be shared, used, and disclosed as provided by 31 U.S.C. § 3733.

### **Document Request:**

In accordance with the definitions and instructions set forth in **Attachment A** and the production specifications in **Attachment B**, you are required by this Demand to produce any and all documents in your possession, custody or control responsive to the document requests set forth in **Attachment C**.

You must make this material available to Department of Justice Trial Attorney Jessica M. Bergin and Assistant United States Attorney David Thiess, who have been designated as False Claims Act custodians in this case. Ms. Bergin may be contacted at (202) 305-4207 or Jessica.Bergin@usdoj.gov, and Mr. Thiess may be contacted at (916) 554-2825 or David.Thiess@usdoj.gov, if you have any questions. These documents shall be produced no later than thirty (30) days from the receipt of this Demand, at U.S. Department of Justice, Civil Division, 175 N Street NE, Room 9.108, Washington, D.C., 20002, or at another time or location to be mutually agreed upon by you and the False Claims Act custodian. The production of documentary material in response to this Demand must be made under a sworn certificate in the form printed in this Demand.

### Written Interrogatories:

In accordance with the definitions and instructions set forth in **Attachment A**, you are required by this Demand to answer the interrogatories set forth in **Attachment D**. The answers to interrogatories shall be submitted no later than twenty (20) days from the receipt of this Demand, at U.S. Department of Justice, Civil Division, 175 N Street NE, Room 9.108, Washington, D.C., 20002, or at another time or location to be mutually agreed upon by you and the False Claims Act custodian. The interrogatories shall be answered separately and fully in writing under oath and also shall be submitted under a sworn certificate in the form printed in this Demand. If you object to any interrogatory, the reasons for the objection shall be stated with specificity.

Issued at Washington, DC, this 27th day of September , 2023.

Jamie Ann Yavelberg
Director
Commercial Litigation Branch

### FORM OF CERTIFICATE OF COMPLIANCE<sup>1</sup>

I have responsibility for producing the documents requested in Civil Investigative Demand No. 23-1306. I hereby certify that all the materials required by that Civil Investigative Demand which are in the possession, custody or control of the person to whom the Demand is directed have been submitted to a custodian named therein.

If any such material has not been produced because of a lawful objection, the objection to the document request and the reasons for the objection have been stated.

	Signature
	Title
SWORN TO before me this day of, 2023	
NOTARY PUBLIC	

<sup>&</sup>lt;sup>1</sup> In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

### FORM OF CERTIFICATE OF COMPLIANCE<sup>1</sup>

I have responsibility for answering interrog	gatory numbers	in Civil	
Investigative Demand No. 23-1306. I hereby certification	fy that all the informatio	n required by the	
Civil Investigative Demand and in the possession,	custody, control, or know	wledge of the person	
to whom the Civil Investigative Demand is directe	d has been submitted. T	o the extent	
information has not been furnished, the information is identified and the reasons why the			
information was not furnished are set forth with pa	articularity. Additionally	, if any such	
information has not been produced because of a la			
interrogatory and the reasons for the objection hav		nder penalty of perjury	
that the foregoing interrogatory responses are true	and correct.		
	Cianotura		
	Signature		
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<b>SWORN TO</b> before me thisday of			
, 2023			
NOTABY BUDLIC			
NOTARY PUBLIC			

<sup>&</sup>lt;sup>1</sup> In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

### **VERIFIED RETURN OF SERVICE**

I,	, an e	mployee of the Ur	nited States working under
the direction and supervisi	on of attorney Jessica Be	ergin in connection	n with a false claims law
investigation, hereby certi	fy that at the time of	, on the	day of,
2023, I personally served	Civil Investigative Dema	and No. 23-1306 o	n
	, by delivering an execu	ted copy of such I	Demand at:
I dooloro undor nor	alter of poriors that the f	aracaina is trus ar	. nd correct. Executed on this
			id correct. Executed on this
day of	, 2023	•	
		Signature	
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#### ATTACHMENT A TO CIVIL INVESTIGATIVE DEMAND NO. 23-1306

### **DEFINITIONS AND INSTRUCTIONS**

#### A. DEFINITIONS

- 1. Unless specified otherwise, the terms "You" or "Your" mean Global Wound Care Medical Group, and any and all predecessors, successors, affiliates, subsidiaries, parent companies, branches, divisions, offices, units, officers, directors, employees, agents, consultants, and assigns.
- 2. Unless specified otherwise, the term "Wound Pros" means Wound Pros, P.C. f/k/a Wound Pros LLC, Global Wound Care Medical Group, Ohio Wound Care Physicians Inc., Wound Care Medical Group P.C., Wound Pros Arizona, P.C., Wound Pros Doctors P.C., Wound Pros Florida, P.A. f/k/a Wound Pros Florida, Inc., Wound Pros Georgia P.C. f/k/a Wound Pros Georgia Inc., Wound Pros Michigan, P.C. f/k/a Wound Pros Michigan Inc., Wound Pros New York Inc., Wound Pros Ohio Inc., Wound Pros Tennessee, P.C. f/k/a Wound Pros Tennessee Inc., Wound Pros Texas PLLC f/k/a Wound Pros Texas Inc., WP Texas Medical Group P.C., Washington Wound Pros Nevada, P.C., Wound Pros Holdings, P.C., Wound Pros Enterprises LLC, Wound Pros Technology Inc., Wound Pros Ventures, LP, and Wound Pros Management Group, Inc.; and any and all predecessors, successors, affiliates, subsidiaries, parent companies, branches, divisions, offices, units, officers, directors, employees, agents, consultants, and assigns.
- 3. "Communication" is used in the broadest sense permitted by Federal Rules of Civil Procedure 26(b), 34(a) and 45(a) and means any transmission or exchange of information orally or in writing, and include, but are not limited to, any emails and text message conversations (including those stored on organization and personal devices).
  - 4. "CPT code" means any Current Procedural Terminology code.
- 5. "DME" means any durable medical equipment, including, but not limited to, all items that can be classified using the following HCPCS and/or CPT codes: A4245-A5120, A6000-A6461, and L4360-L4387.
- 6. "Document" and "documents" are used in the broadest sense permitted by Federal Rules of Civil Procedure 26(b), 34(a) and 45(a) and include, but are not limited to, any hard copy or electronically stored information, emails, and text message conversations.
- 7. "Employee" shall mean any person including, but not limited to, an employee, volunteer, independent contractor or agent, all past and present directors, officers, agents, representatives, accountants, advisors, and consultants who acted or purported to act on Your or Wound Pros' behalf or who performed any service for You or Wound Pros under Your or Wound Pros' name, whether on a full-time, part-time, piece-work, commission or other basis and whether paid or unpaid.

- 8. "Federal healthcare program" means any healthcare program administered or funded wholly or in part by the United States, including, but not limited to, Medicare, Medicaid, TRICARE, CHAMPVA and other VA health care programs and services, the Federal Employee Health Benefits Program, and the Federal Bureau of Prisons Health Services Program.
  - 9. "HCPCS code" means any Healthcare Common Procedure Coding System code.
  - 10. "Identify" means to provide the following information in Your response:
    - a. With respect to a natural person:
      - (i) the person's full name;
      - (ii) the name of the person's current or last known employer;
      - (iii) the person's title and position, if known;
      - (iv) the person's current or last known business and home address and telephone number; and
      - (v) if applicable, the person's National Provider Identifier ("NPI");
    - b. With respect to a corporation, partnership, joint venture, or other entity:
      - (i) the name of the entity;
      - (ii) the addresses and telephone numbers of its principal office(s);
      - (iii) the tax identification number; and
      - (iv) if the entity is a medical provider, the entity's NPI, Medicare provider number, and CMS Certification Number ("CCN"), if applicable;
    - c. With respect to documents:
      - (i) the title of the document;
      - (ii) the date of the document;
      - (iii) a description of the type of document;
      - (iv) a summary of the document's contents;
      - (v) the present location of the original and all existing copies of the document;
      - (vi) a list of all intended recipients of the document, including, but not limited to, all addressees, and all persons who were supposed to receive a copy of the document (*i.e.*, through "cc" or "bcc"); and
      - (vii) the identity of the author and a list of all persons who participated in the creation of the document.
- 11. "Non-physician practitioner" means any practitioner of healthcare services who is not also a doctor of medicine or a doctor of osteopathic medicine.
- 12. "Physician" means any provider of healthcare services who is a doctor of medicine or a doctor of osteopathic medicine
- 13. "Provider" means any physician, physician group, hospital, laboratory, skilled nursing facility, home health agency, hospice, board and care facility, physician assistant, nurse,

nurse practitioner, medical assistant, or any other person or entity who provides any healthcare services, including any non-physician practitioner who provides any healthcare services.

- 14. "Relating to" and "related to" mean consisting of, concerning, referring to, reflecting, supporting, evidencing, prepared in connection with, used in preparation for, or being in any way legally, logically, or factually connected to the matter discussed.
- 15. "Skin substitute" means any graft used to assist with wound healing, such as non-autologous human skin (dermal or epidermal, cellular and acellular) grafts, non-human skin substitute grafts, and biological products (placental and amniotic skin substitutes), including, but not limited to, all items that can be classified using the following HCPCS and/or CPT codes: C5271-C5278 and Q4101-Q4284.
- 16. "Text message conversations" refers to any and all electronic communications (other than emails) that can or do contain text, regardless of the format of the communications, the application or platform used to send or receive the communications, and whether the communications are immediately retrievable or retrievable only via a forensic extraction, including, but not limited to, those occurring in or via SMS, MMS, EMS, iMessage, Facebook chat, Facebook messenger, Google Talk (formerly Gchat), Blackberry Messenger (BBM), Skype, GroupMe, AIM, WhatsApp, Slack, Snapchat, Signal, WeChat, or company-deployed electronic health records or communications platforms, as well as, recoverable deleted data, backup files (e.g., iCloud or iPhone backup files), and archive snapshots.
- 17. The terms "and" and "or" shall be construed conjunctively or disjunctively so as to make each particular request inclusive rather than exclusive.
- 18. The terms "any" and "all" shall be construed conjunctively or disjunctively so as to make each particular request inclusive rather than exclusive.
- 19. The singular and plural forms of any word shall be construed interchangeably so as to bring within the scope of this Demand any document which might otherwise be construed as outside its scope.

### **B. INSTRUCTIONS**

- 1. Relevant Time Period: Unless otherwise stated in any specific request below, each request covers the relevant time period since January 1, 2016.
- 2. This Demand is continuing in nature. If You become aware of or acquire possession, custody, or control of additional documents that are responsive to this Demand, or if You become aware of or acquire additional information that is responsive to these interrogatories, You shall promptly produce such additional documents or supplement Your interrogatory responses.
- 3. This Demand applies to all documents and information in Your possession, custody, or control regardless of their location and regardless of whether such documents or

information are held by Your current or former employees, including, but not limited to, inhouse IT specialists and technicians, IT specialists and technicians to whom digital services have been out-sourced.

- 4. All documents produced pursuant to this Demand are to be organized in such a manner that all documents relating to a particular request are grouped together and identified as being responsive to that request.
- 5. If any document which is otherwise responsive to this Demand is not disclosed because of a claim of privilege or other objection, You shall identify such documents on a Privilege Log. The Privilege Log shall be produced in Excel or Word format and include the following information:
  - (a) the basis for the assertion of the privilege or objection;
  - (b) the type of document (e.g., letter, memorandum, email, etc.)
  - (c) the name and title of the author (and if different, the preparer and signatory);
  - (d) the name(s) and title(s) of the individual(s) to whom the document was addressed;
  - (e) the name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
  - (f) the date of the document;
  - (g) number of pages;
  - (h) a general description of the subject matter; and
  - (i) the Request(s) to which the document is responsive.
- 6. When a requested document contains both privileged and non-privileged material, the non-privileged material must be disclosed to the fullest extent possible. If a privilege is asserted with regard to a part of the material contained in a document, the party claiming the privilege must clearly indicate the portions as to which the privilege is claimed. When a document is redacted or altered in any fashion, identify as to each document the reason for the redaction or alteration, the date of the redaction or alteration, and the person performing the redaction or alteration. Any redaction must be clearly visible on the redacted document.
- 7. If any document otherwise responsive to this Demand is not produced because it was lost, destroyed, or discarded:
  - (a) identify the document by type, date, and title;

- (b) identify the person who last had custody or control over the document;
- (c) state the date on which the document was destroyed or was discovered to have been lost;
- (d) if the document was destroyed, state why it was destroyed and identify the person(s) who destroyed it;
- (e) if the document was lost, describe the circumstances in which its loss was discovered, state the date that it was last seen or otherwise accounted for, and identify the person(s) who discovered its loss and who last saw or otherwise accounted for it;
- (f) identify all persons who have knowledge pertaining to the destruction or loss of the document, giving a concise but complete statement of the knowledge You claim each such person has;
- (g) identify all persons who have knowledge of the contents of each lost or destroyed document, giving a concise but complete statement of the knowledge You claim each such person has; and
- (h) produce all existing indices, lists, or other documents in Your possession, custody, or control that reflect the existence of such lost or destroyed documents, and/or their transfer or destruction.
- 8. If no documents exist that are responsive to a specific document request, a written statement to that effect shall be provided at the time of production.
- 9. To the extent that documents responsive to this Demand are in the possession, custody, or control of third parties, this Demand requires a statement to that effect at the time of production, specifically providing the name, address, telephone number and principal contact of the third party, and shall further identify those documents in said third party's possession.
- 10. Please produce imaged hard copy and electronic documents according to the Specifications for Production of Electronically Stored Information and Digitized Images at **Attachment B**.
- 11. For each interrogatory and subpart thereof, You must respond separately and in writing. Your responses must identify all documents that You used, referenced, or relied upon in Your written responses.
- 12. If You withhold any information responsive to any interrogatory based on a claim of privilege or other objection: (a) furnish the basis for the assertion of the privilege or objection, (b) identify all individuals who could respond to the interrogatory with regard to the information that is being withheld, and (c) set forth the general subject matter and the specific interrogatory or interrogatories to which each individual could testify.

13. When providing the name of an individual in response to any interrogatory or individuals identified pursuant to Instruction 12 above, provide the individual's last known address, telephone number, email address, or other contact information, as well as the individual's relationship to You. If the individual is or was an employee, provide the individual's title and dates of employment.

#### ATTACHMENT B TO CIVIL INVESTIGATIVE DEMAND NO. 23-1306

# Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

## Collection of Electronically Stored Information (ESI)

Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process. Consideration should also be given as to whether production media should be encrypted when producing to the government when required by law (i.e. Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), etc. *See* Section 24 below.

## 1. Specification Modifications

Any modifications or deviations from the Production Specifications may be done only with the express permission of the government and these modifications or deviations should be communicated to the government and approved by the government in written form. Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the government to facilitate their production.

## 2. Production Format of ESI and Imaged Hard Copy Documents

Responsive ESI and imaged hard copy shall be produced in the format outlined below. All ESI, except as outlined below in sections 5-21, shall be rendered to TIFF image format, and accompanied by an Opticon/Concordance® Image Cross Reference file. All applicable metadata/database (see section 3 below) shall be extracted and provided in Concordance® load file format.

- a. Image File Format: All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image.
- b. When producing black and white paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi, 1 bit, single-page TIFF files, CCITT Group IV (2D Compression). When producing in *color*, paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi single-page JPG. Images should be uniquely and sequentially Bates numbered and unless otherwise specified, Bates numbers should be an endorsement on each image.
  - All TIFF file names shall include the unique Bates number burned into the image. (See section 22, below, regarding Bates number instructions.)
  - ii. All TIFF image files shall be stored with the ".tif" extension.

- Images without corresponding extracted text shall be OCR'd using standard COTS products.
  - An exception report shall be provided when limitations
    of paper digitization software/hardware or attribute
    conversion do not allow for OCR text conversion of
    certain images. The report shall include the DOCID or
    Bates number(s) corresponding to each such image.
- iv. All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, shall be delivered on a single piece of media.
- v. No image folder shall contain more than 2,000 images.
- c. Opticon/Concordance® Image Cross Reference file: Images should be accompanied by an Opticon load file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the relative image file path for each Bates numbered page. The Opticon/Concordance® Image Cross Reference file is a page level load file, with each line representing one image.

## Below is a sample:

REL00000001,..\IMAGES\001\REL000000001.TIF,Y,,, REL000000002,..\IMAGES\001\REL000000002.TIF,,,, REL000000003,..\IMAGES\001\REL000000003.TIF,,,, REL000000004,..\IMAGES\001\REL000000004.TIF,Y,,, REL000000005,..\IMAGES\001\REL000000005.TIF,,,,

## The fields are, from left to right:

- Field One (REL000000001) the Bates Number. This value must be unique for each row in the OPT file. The first page of each document must match the DOCID or BEGDOC# value of the respective document.
- Field Two (blank) the volume identifier. This field is not required.
- Field Three (.\IMAGES\001\REL000000001.TIF) The relative file path to the image to be loaded.
- Field Four (Y) the document marker. A "Y" indicates the start of a unique document.
- Field Five (blank) The folder indicator. This field is not required, and typically is not used.
- Field Six (blank) The box indicator. This field is not required, and typically is not used.
- Field Seven (blank) The page count. This field is not required.
  - d. Concordance® Load File: Images should also be accompanied by a flat, document-level load file to provide the metadata and native files containing delimited text that will populate fields in a searchable, flat

database environment. The file encoding must be one of four types: Western European (Windows), Unicode (UTF16), Big-Endian Unicode or UTF8. The file should contain the required fields listed below in section 3.

1. Text delimited load files are defined using the standard Concordance delimiters. For example:

Field Separator
Text Qualifier
Newline
Multi-value
Nested values

¶ or Code 020
p or Code 254
nor Code 174
y or Code 059
\or Code 092

- 2. This load file should contain the relative file path to the individual multi-page, document level text files.
- This load file should also contain the relative file path to all provided native files, such as Microsoft Excel or PowerPoint files.
- 4. There should be one line for every record in a collection.
- 5. The load file must contain a header listing the metadata/database fields contained within. For example, if the data file consists of a First Page of a Record (BegDoc#), Last Page of a Record (ending Bates / ENDDOC#), DOCID, DOCDate, File Name, and a Title, then the structure may appear as follows:

# $\verb|bBEGDOC| \verb||pENDDOC| \verb||pDOCID|| \verb||pDOCDATE|| \verb||pFILENAME|| \verb|pTITLE||$

- d. The extracted/OCR text should be provided for each document as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.
- e. **Directory and folder structure:** The directory structure for productions should be: \CaseName\LoadFiles

\CaseName\Images < For supporting images (can include subfolders as needed, should not include more than 2,000 files per folder)
\CaseName\Natives < Native Files location (can include subfolders as needed, should not include more than 2,000 files per folder)
\CaseName\Text < Extracted Text files location (can include subfolders as needed, should not include more than 2,000 files per folder)
\CaseName\Translated Images < For supporting images of translated documents (as needed for rendered translated documents; can include subfolders as needed, should not include more than 2,000 files per folder)

\CaseName\Translated Text < Translated Text files location (as needed for translated text; can include subfolders as needed, should not include more than 2,000 files per folder).

## 3. Required Metadata/Database Fields

A "√" denotes that the indicated field should be present in the load file produced. "Other ESI" includes data discussed in sections 5 – 21 below, but does not include email, email repositories (section 11), "stand alone" items (section 12), imaged hard copy material (section 9) and production from ESI collected from Smart Phones, Mobile Devices and Other Technology (section 13). Email, email repositories, and "stand alone" materials (section 12) should comply with "Email" column below. Imaged hard copy materials should comply with the "Hard Copy" column. Production from ESI collected from Smart Phones, Mobile Devices and Other Technology should comply with the requirements of section 13. The parties will meet and confer about any field which cannot be populated automatically (i.e. would require manual population of information).

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
COLLECTION SOURCE	Name of the Company/Organization data was collected from	Text	160	1	✓	✓
SOURCE ID (BOX #)	Submission/volume/box number	Text	10	1	1	1
CUSTODIAN	Custodian/Source - format: Last, First or ABC Dept.	Text	160	1	1	1
DUPECUSTODIAN	Custodian/Source – all custodians who had the document before deduplication; format: Last, First or ABC Dept.	Text – semicolon delimited	Unlimited		1	✓
DUPECUSTODIAN FILE PATH	Listing of all the file locations of the document before deduplication	Text – semicolon delimited	Unlimited		1	1
AUTHOR	Creator of the document	Text	500			1
BEGDOC#	Start Bates (including prefix) - No spaces	Text	60	1	1	1
ENDDOC#	End Bates (including prefix) - No spaces	Text	60	1	<b>√</b>	1
DOCID	Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)	Text	60	1	1	1

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
PGCOUNT	Page Count	Number	10	1	1	1
GROUPID	Contains the Group Identifier for the family, in order to group files with their attachments	Text	60	·	1	1
PARENTID	Contains the Document Identifier of an attachment's parent	Text	60		1	1
ATTACHIDS	Child document list; Child DOCID or Child Start Bates	Text – semicolon delimited	Unlimited	1	1	1
ATTACHLIST	List of Attachment filenames	Text – semicolon delimited	Unlimited		✓	1
BEGATTACH	Start Bates number of parent	Text	60	1	1	1
ENDATTACH	End Bates number of last attachment	Text	60	1	1	1
RECORD TYPE	Use the following choices: Image, Loose Email, E-mail, E-Doc, Attachment, Hard Copy or Other. If using Other, please specify what type after Other	Text	60	1	✓	✓
FROM	Sender (i.e.: e-mail address, Last name, First name)	Text	160		1	1
ТО	Recipient (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		1	1
CC	Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		1	✓
BCC	Blind Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		1	1
SUBJECT	Subject line of email	Text	Unlimited		1	
TITLE	Document Title	Text	Unlimited			1
CONVINDEX	E-mail system ID used to track replies, forwards, etc.	Text	Unlimited		1	

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
DOCDATE	Last Modified Date for files and Sent date for email, this field inherits the date for attachments from their parent. Do not provide 00/00/0000.	Date	MM/DD/ YYYY		✓	1
TEXT FILEPATH	Relative file path of the text file associated with either the extracted text or the OCR	Text	Unlimited	1	1	1
DATE TIME SENT	Date and time Sent (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S		✓	
DATE TIME CRTD	Date Created (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S		✓	✓
DATE TIME SVD	Date Saved (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S		✓	✓

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
DATE TIME MOD	Date Last Modified (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S	Сору	√	√
DATE TIME RCVD	Date Received (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S		✓	
DATE TIME ACCD	Date Accessed (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/ YYYY HH:MM:S S		✓	✓
TIME ZONE OFFSET	Time zone of collection locality, relative to Coordinated Universal Time (UTC). E.g., for US Central Standard Time (CST), the value for this field should be -6.0	Decimal	10		1	
FILE SIZE	Native File Size in KBs	Decimal	10			1
FILE NAME	File name - name of file as it appeared in its original location	Text	Unlimited			1
APPLICATION	Application used to create native file (e.g. Excel, Outlook, Word)	Text	160		1	1
FILE EXTENSION	Extension for the file (e.gdoc, .pdf, .wpd)	Text	10		1	1

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
FILEPATH	Data's original source full folder path	Text	Unlimited	Сору	<b>√</b>	1
NATIVE LINK	Relative file path location to the native file	Text	Unlimited		1	1
FOLDER ID	Complete E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. folder or binder name)	Text	Unlimited	1	1	
HASH VALUE	Identifying value of an electronic record that is used for deduplication during processing. MD5 or SHA1 hash algorithms may be used, but must be kept consistent throughout all productions and communicated to Government.	Text	Unlimited		✓	1
MESSAGEHEADER	E-mail header.	Text	Unlimited		1	
ATTACHMCOUNT	Number of attachments (any level child document) associated with a ParentID	Text	10		1	
FILE TYPE	Description that represents the file type to the Windows Operating System. E.g., Adobe Portable Document Format, Microsoft Word 97 – 2003, or Microsoft Office Word Open XML Format.	Text	160		1	✓
HAS HIDDEN CONTENT	Identifies whether the document has comments, track changes or other hidden content or data associated with it	Text	Yes/No		1	1
MESSAGE TYPE	Exchange Message class or equivalent	Text	60		1	
EXTENDED PROPERTIES		Text	Unlimited		1	1

Field name	Field Description	Field Type	Field Value	Hard Copy	E- mail	Othe r ESI
HAS REDACTIONS	Identifies whether a record has been produced with redactions; should be populated with Y for records with redactions and N for records without redactions.	Text	Yes/No	1	✓	✓
HAS TRANSLATIONS	Identifies whether a document has been produced with translated text or audio contains a transcript	Text	Yes/No	1	1	1

# 4. Search, De-Duplication, Near-Duplicate Identification, Technology Assisted Review, E-mail Conversation Threading and Other Culling Procedures

- De-duplication of exact hash copies shall be performed globally across all custodians. The custodian of each record shall be populated in the DupeCustodian field.
  - All files found on the National Institute of Standards and Technology (NIST) list, commonly referred to as deNISTing, should be excluded from delivery to the Government. All available metadata from files withheld from delivery due to the deNISTing process will be available upon request.
- b. All files should be globally de-duplicated with the following conditions:
  - The "DupeCustodian" metadata field (listing of all custodians who had the document before de-duplication) must be provided with the document production.
  - The "DupeCustodian File Path" metadata field (listing all the file locations of the document before de-duplication) must be provided with the document production.
  - iii. All files and metadata for the duplicate documents removed during deduplication must be preserved and available for production upon request.
  - iv. No customization of hashing may occur without prior express approval by the Government.
  - v. De-duplication must be done by document family, not by individual document.
  - vi. A detailed description of the steps taken to de-duplicate (including the process of obtaining hash values) must be provided to the Government. For every production after the first, a separate Unified Custodian overlay shall be provided. If no overlay is necessary due to the fact that no documents deduped out in connection with previously produced documents, this shall be

expressly stated in the cover letter accompanying the subsequent production(s).

c. The Producing Party shall not use any other procedure to cull, filter, group, separate or de-duplicate, or near-deduplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the government. All objective coding (e.g., near duplicate ID or e-mail thread ID) shall be discussed and produced to the government as additional metadata fields. The Producing Party will not employ analytic software or technology to search, identify, or review potentially responsive material, including but not limited to, technology assisted review or predictive coding, without first discussing with the government.

#### 5. Hidden Text

All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. Except for Adobe PDF files, for any files that cannot be expanded, the native files shall be produced with the image file. If an Adobe PDF's hidden text cannot be expanded and rendered in an image file, it need only be produced in native form if individually requested by a specific document identifier or bates number.

### 6. Embedded Files and File Links

All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production, the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

The parties shall meet and confer regarding how to treat file links, including links within e-mails to centralized document repositories (e.g. MS OneDrive and Google Drive).

# 7. Image-Only Files

All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool and other screenshots, etc., as well as all other images that contain text) shall be produced with OCR text and metadata/database fields identified in section 3 for "Other ESI."

## 8. Encrypted Files

Any data (whether individual files or digital containers) that is protected by a password, encryption key, digital rights management, or other encryption scheme, shall be decrypted prior to processing for production.

- a. The unencrypted text shall be extracted and provided per section 2.d. The unencrypted files shall be used to render images and provided per sections 2.a and 2.b. The unencrypted native file shall be produced pursuant to sections 10-21.
  - If such protected data is encountered but unable to be processed, each file or container shall be reported as an exception in the accompanying Exception Report (pursuant to section 27) and shall include all available metadata associated with the data, including custodian information.

## 9. Production of Imaged Hard Copy Records

All imaged hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID).

- a. Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder).
  - The first document in the collection represents the parent document and all other documents will represent the children.
- b. All imaged hard copy documents shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.
  - All objective coding (e.g., document date or document author) should be discussed and could be produced to the government as additional metadata/database fields should they be deemed as necessary.

## 10. Production of Spreadsheets and Presentation Files

All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed "as kept in the ordinary course of business" state (i.e., in native format), with an associated placeholder image and endorsed with a unique Bates number. *See* section 22 below. The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata.

## 11. Production of E-mail Repositories

E-mail repositories, also known as e-mail databases (e.g., Outlook PST, Lotus NSF), can contain a variety of items, including: messages, calendars, contacts, tasks, etc. E-mail database systems should not be produced without consultation with and written consent of the government about the format for the production of such databases.

# 12. Production of Items Originally Generated in E-mail Repositories but Found and Collected Outside of E-mail Repositories, i.e., "Stand-alone" Items

Any parent e-mail or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of e-mail repositories (e.g., items having extensions .msg, .htm, .mht, etc.), shall be produced with the "Loose E-mail" metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

# 13. Production of ESI Collected from Mobile Devices, Messaging Platforms, Workplace Collaboration Tools and Other Technologies

The responding party shall identify, collect, and produce any and all data which is responsive to the requests, collected from mobile devices, messaging platforms, workspace collaboration tools and other technologies. These technologies include, but are not limited to smart phones, cell phones, tablets, PDAs, Blackberry, smart phone data, tablet data, voicemail messaging data, instant messaging, chat messaging, text messaging, Slack, conference call data, video/audio conferencing, workspace collaboration tools (e.g., GoTo Meeting, WebEx, MS Teams, Zoom), and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the government about the format for the production of such data.

The expectation of the government is that all familial relationships for all data will be maintained. Similar to email conversations and families, the expectation is that all messages/texts in a conversation will be provided the same conversation index and groupid data (maintaining the familial relationship) allowing the government to read the entire conversation in context. Messages should be produced to align with the formats listed in section 2 and as individual Unicode text files, and attachments should be produced as native files with images and OCR text.

While the parties shall meet and confer on precise metadata formats, as an example, metadata collected from mobile devices shall be provided in formats such as the following:

	Eiold					Mol	Mobile Cellebrite Categories	e Categories			
Field Name	Description	Mobile	Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
TXT- ROWNUMBER	Row number.	1	#	#	#	#	#	#	#	#	#
TXT- CHATNUMBER	Chat number, identifies chat groups.	1	Chat #								
TXT- STARTTIME	Start date-time for conversation, calendar item.	4	Start Time: Date								Start Date: Date
TXT-ENDTIME	End date-time for calendar item.	>									End Date: Date
TXT- LASTACTIVITYTIME	End date-time for conversation.	>	Last Activity: Date								
TXT- PARTICIPANTS	Who was involved in the conversation, meeting.	>	Participa nts		Party						Attendees
TXT- MESSAGENUMBER	Individual identifier for message.	>	Instant Message #								
TXT-BODY	Body of the chat, message, item.	1	Body	Body	Message					Body	
TXT-STATUS	Whether the text was Sent or Read on the device.	>	Status	Status	Status			Į			Status
TXT-LOCATION	GPS Information.	1	Location				Location				Location
TXT- TIMESTAMP	Timestamp of item. Equivalent to DateReceived for incoming items or to	>	Timesta mp: Date	Date	Date	Date		Timestamp -Date	Timestamp- Date		

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	Field					Mol	Mobile Cellebrite Categories	Categories			
Field Name	Description	Mobile	Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
	DateSent for outgoing items.										
TXT-READDATE	Date read	>	Read: Date		Read- Date		Read-Date				
TXT-DELETED	Indicates whether a message was deleted and recovered by Cellebrite.	>	Deleted - Chat	Deleted		Deleted	Deleted	Deleted	Deleted	Deleted	Deleted
TXT- STARREDMESSAGE	Notes whether the message was flagged.	>	Starred				Starred message				
TXT-THREAD-	Populate with the DOCID of the first text in the chat conversation to allow the entire chat conversation to be grouped as a family. (Sort each device by Chat Number and then by Row Number to assign TXT-THREAD-GROUP identifier). This is NOT the BEGATTACH field or	\$	Chat #								

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	Ecold			3		Mol	oile Cellebrit	Mobile Cellebrite Categories			
Field Name	Description	Mobile	Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calend
	Relativity Group Identifier.										
TXT-SMSC	Short Message Service Center (handles SMS text messages on behalf of phone service	>			SMSC						
DIRECTION	Direction of communication; Outgoing or Incoming.	>		Direction	Direction	Direction	Direction				
IMPORTANCE		>		Priority		Priority					Priority
ACCOUNT	Account identifier for device user: email address, phone number, account	>		Name		Account		Name			
DURATION	Duration time of call, voice message, audio, video in HH:MM:SS format, e.g. 00:00:32	>	1 11	1				Duration	Duration	1 2 11	1 1

#### 14. Production of Social Media

Prior to any production of responsive data from social media (e.g., Twitter, Facebook, LinkedIn, etc.), the producing party shall first discuss with the government the potential export formats before collecting the information, to ensure it is collected and produced in a way that preserves the original metadata, has a clear chain of custody, and provides as much information as possible regarding the source and history of each individual communication.

Social media platforms offer different functions, forms of content, and capability for downloading accounts. Because of these differences, prior to collection of social media data, the producing party must discuss with the government the available export and production methods and formats that the producing party is considering. Unless the government agrees to an alternative in writing, regardless of the social media platform, productions of social media content must meet the following general requirements: (1) separate (2) searchable (3) static images of (4) each responsive posting on the social media platform, (5) all related content (e.g., comments, likes, share or re-transmittal information, images, videos, linked documents and content), and (6) associated metadata (e.g., user name(s), date, and time of all posts, comments, likes, share or re-transmittals).

These general requirements are in addition to any more specific requirements in a particular request (e.g., geolocation data), and the producing party must ask the government about any perceived conflict between these requirements and another source of specifications or requirements. If available from the social media platform or through social media data processing software, files that facilitate interactive review of the data (i.e., html files) as well as load files in .csv format must be produced with the associated content.

#### 15. Production of Structured Data

Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, proprietary timekeeping, accounting, sales rep call notes, CRMs, SharePoint, etc.), the producing party shall first identify the database type and version number, discuss providing the database dictionary (in whole or part) and any user manuals, or any other documentation describing the structure and/or content of the database and a list of all reports that can be generated from the database. Upon consultation with and written consent of the government, if a report is provided, the standard format of that report provided should be in comma separated values (.csv) format. The information contained in any such report must be thoroughly explained to the government before production.

## 16. Production of Photographs with Native File or Digitized ESI

Photographs shall be produced as single-page JPEG files with a resolution equivalent to the original image as they were captured/created. All JPEG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for "Other ESI."

## 17. Production of Images from which Text Cannot be OCR Converted

An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.

# 18. Production of Translated Text with Non-English Language ESI or Documents

To the extent translated text is available to the producing party through machine language translation, such translations shall be provided to the government with the production. The producing party shall provide the original extracted text as well as the translated extracted text in load ready format. The translated text and images of translated documents shall be provided as a separate folder volume to the main production. The parties shall meet and confer regarding any required translated text redactions.

## 19. Production of Audio File Transcripts

To the extent audio files are produced and transcripts are available to the producing party through machine transcription, such transcripts shall be provided to the government with the production. The producing party shall provide the audio file transcript as a text file in load ready format like any other text file named by the BEGDOC#. The parties shall meet and confer regarding any required audio file redactions.

## 20. Production of ESI from Non-PC or Non-Windows-based Systems

If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes, and UNIX machines, Android device, etc.), the ESI shall be produced after discussion with and written consent of the government about the format for the production of such data.

# 21. Production of Native Files (When Applicable Pursuant to These Specifications)

Production of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for "Other ESI" as outlined in section 3 as well as a placeholder image which indicates a native file is being produced.

ESI shall be produced in a manner which is functionally usable by the government. The following are examples:

- a. AutoCAD data, e.g., DWG and DXF files, shall be processed/converted and produced as single-page JPG image files and accompanied by a Concordance® Image formatted load file as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
  - GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.

 Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

### 22. Bates Number Convention

All images should be assigned Bates numbers before production to the government. Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page. The numbers should be endorsed on the actual images at a location that does not obliterate, conceal, or interfere with any information from the source document. Native files should be assigned a single Bates number for the entire file which will represent the native document in the Opticon/ Concordance® Image Cross Reference file. The load file will include a reference to the native file path and utilize the NATIVELINK metadata field). The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique number given sequentially (i.e. page one of document is PREFIX00000000001, page two of the same document is PREFIX00000000002) to each page (when assigned to an image) or to each document (when assigned to a native file). If the parties agree to a rolling production, the numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use "dot notation." Below is a sample of dot notation:

	Document #1	Document #2
Page #1	PREFIX0000000001	PREFIX00000000002
Page #2	PREFIX0000000001.002	PREFIX0000000002.002
Page #3	PREFIX0000000001.003	PREFIX0000000002.003

## 23. Media Formats for Storage and Delivery of Production Data

Electronic documents and data shall be delivered on any of the following media:

- a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications; Blu-ray.
  - External hard drives (USB 3.0 or higher, formatted to NTFS format specifications) or flash drives
- b. Government approved File Transfer Protocol (FTP) technologies.
  - Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
- c. Media should be labeled with the case name, production date, Bates range, and producing party.

## 24. Virus Protection and Security for Delivery of Production Data

Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the government. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. All encryption software shall be used with approval by and with the written consent of the government.

## 25. Compliance and Adherence to Generally Accepted Technical Standards

Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology ("NIST" at www.nist.gov), U.S. National Archives & Records Administration ("NARA" at www.archives.gov), American Records Management Association ("ARMA International" at www.arma.org), American National Standards Institute ("ANSI" at www.ansi.org), International Organization for Standardization ("ISO" at www.iso.org), and/or other U.S. Government or professional organizations.

#### 26. Read Me Text File

All deliverables shall include a "read me" text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths, and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

## 27. Exception Report

An exception report, in .csv format, shall be included, documenting any production anomalies during the collection, processing, and production phases. The report shall provide all available BEGDOC# or DOCID values and metadata listed in section 3, including but not limited to file names and file paths for all affected files.

## 28. Transmittal Letter to Accompany Deliverables

All deliverables should be accompanied by a transmittal letter including the production date, case name and number, producing party name, and Bates range produced. Technical instructions on how to decrypt media should be included in the transmittal letter but the password should be transmitted separately.

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#### ATTACHMENT C TO CIVIL INVESTIGATIVE DEMAND NO. 23-1306

## **DOCUMENT REQUESTS**

You are required by this Demand to produce any and all of the following documents in Your possession, custody, or control:

- All documents reflecting any formal or informal contracts and agreements between You
  or Wound Pros and the persons and entities identified in connection with interrogatory 1,
  including all documents and communications reflecting any compensation, payment,
  commissions, bonuses, reimbursement of expenses, risk sharing, or any other
  remuneration or benefits of any kind.
- 2. All documents and communications concerning any compensation, commission, bonus, or any other remuneration or benefits of any kind offered and/or paid by or on behalf of You or Wound Pros to any person or entity that provides, supervises, directs, refers, or otherwise causes the provision or billing of the federal healthcare programs for any skin substitute products or services by or on behalf of You or Wound Pros, including, but not limited to, all documents and communications related to any fair market value assessment of that compensation.
- 3. All personnel evaluations, records, schedules, timesheets, logs, and any other documentation of payments, remuneration, commission, reimbursement of expenses, risk sharing, benefits of any kind, referral, sanction, penalty, disciplinary action, or any other unfavorable action or consequence of any kind relating to the provision of or billing for any skin substitute products or services by or on behalf of You or Wound Pros.
- 4. All documents and communications relating to supervision or direction by any physician affiliated with Wound Pros, including, but not limited to, Dr. Bill J. Releford, Dr. Christopher Otiko, Dr. Owen Ellington, Dr. Joseph M. Palumbo, Dr. Sherman Washington, and Dr. Allyson Pizzo-Berkey, of the provision of any skin substitute products or services by any non-physician practitioner on behalf of Wound Pros.
- 5. All projections, analyses, reports, drafts, reviews, or other documentation reflecting any performance metric, including, but not limited to, revenue, profit, and return on investment ("ROI"), relating to the provision of or billing for any skin substitute products or services by any person or entity affiliated with Wound Pros.
- 6. All documents and communications relating to the ordering by any Wound Pros-affiliated provider of any DME supplies from any Wound Pros-affiliated DME supplier, including the preparation and ordering of pre-made DME kits.
- 7. All formal and informal policies, practices, procedures, guidelines, standard operating procedures, FAQs, training materials, instructions, advice, evaluations, or other guidance in any form relating to (a) supervision of non-physician practitioners, including remote supervision; (b) billing for products and services provided by non-physician practitioners, including billing for services "incident to" services provided by a physician; (c) billing

for products and services provided to patients in hospice, nursing facilities, skilled nursing facilities, or any other board or care facilities; (d) identifying the point of service and the entity that provided any products or services in any documentation related to billing; (e) ordering DME supplies; (f) providing DME to patients; and (g) compliance with federal healthcare program billing requirements, the False Claims Act, Stark Law, Anti-Kickback Statute, or other state and federal laws and regulatory guidance.

- 8. All documents and communications concerning compliance with the requirements of any federal healthcare program, including, but not limited to, all documents exchanged with CMS relating to Your or Wound Pros' ability to participate in the federal healthcare programs, revocation by CMS, and any notifications from CMS regarding any actual, potential, or suspected failure to comply with CMS requirements.
- 9. All formal or informal complaints, allegations, objections, inquiries, or concerns of any kind from any source concerning potential fraud, inappropriate billing, noncompliance with federal healthcare program requirements, unsatisfactory or inappropriate products or services, harm to patients, or violations of statutes or regulations by You or Wound Pros.
- 10. Documents sufficient to show Your corporate structure during the Relevant Time Period from Your corporate parent(s) through any holding companies, limited liability corporations, affiliated corporations or entities, partnerships, or subsidiaries, including specifically identifying the owner(s) of each such entity and the fractional share of ownership.
- 11. Documents sufficient to show Your organizational chart(s) for the Relevant Time Period.
- 12. All documents relied on to answer the interrogatories in **Attachment D**.

#### ATTACHMENT D TO CIVIL INVESTIGATIVE DEMAND NO. 23-1306

#### INTERROGATORIES

- 1. Identify in Microsoft Excel format all persons and entities with which You and/or Wound Pros contracted in connection with providing or billing for healthcare products or services, by specifying in separate fields: (a) the name of the person or entity with which You and/or Wound Pros contracted; (b) the contract name(s); (c) the contract date(s); (d) the contract number(s); (e) all parties to the contract(s); (f) the signatories to the contract(s); (g) the person(s) involved in the contracting process(es); (h) all products and services covered by the contract(s), including whether the contract related in any way to skin substitutes; (i) any amendments to the contract(s); (j) the status of any pending contract negotiations; (k) the reason(s) for any amendment, modification, or termination of any contract; (l) the termination date of the contract; and (m) any documentation related to the contract(s).
- 2. For each Wound Pros entity and affiliate, identify in Microsoft Excel format all owners, investors, and financial supporters of any kind by (a) full name; (b) current or last known business address, home address, and telephone number; (c) ownership share, if applicable; (d) investments and/or financial support provided, including the itemized amount(s) and date(s); (e) return on investment provided by the Wound Pros entity or affiliate to the owner, investor, or financial supporter, if applicable, including the amount(s) and date(s); (f) description of the nature of the ownership, investment relationship, and/or financial support; and (g) any other metric that You or Wound Pros uses to track or quantify the relationship with the owner, investor, or financial supporter.
- 3. For each Wound Pros entity and affiliate, identify in Microsoft Excel format all current and former employees by (a) full name; (b) current or last known business address, home address, and telephone number; (c) NPI, if applicable; (d) job title; (e) job responsibilities; (f) whether the employee was a direct employee, volunteer, independent contractor, agent, director, officer, representative, account, advisor, or consultant; (g) start date; (h) termination date, if applicable; (i) Wound Pros entity with which the individual interacted; (j) locations where any services were provided by the individual; (k) all compensation and benefits of any kind; (l) supervising responsibilities; (m) direct report(s); (n) supervisor(s); and (o) manager(s).
- 4. Identify in Microsoft Excel format all persons and/or entities through whom Wound Pros submits claims for reimbursement to the federal healthcare programs by (a) full name; (b) current or last known business address, home address, and telephone number; (c) NPI, if applicable; (d) tax identification number, if applicable; (e) nature of the relationship with Wound Pros; (f) start date of relationship; (g) end date of the relationship; (h) services provided; (i) dates during which the services were provided; (j) locations where the services were provided; (k) Wound Pros entity on behalf of which the person or entity submitted claims; (l) all compensation and benefits of any kind; and (m) whether the compensation was consistent with fair market value, including the basis for that conclusion.

- 5. Identify in Microsoft Excel format all systems, programs, platforms, software, algorithms, analytics, or other tools used by Wound Pros, including, but not limited to, Slack, RITA, HL7, Smart Sheet, Black Doctor 24/7, Wound Docs, Office Ally, Kareo, Google Drive, Google Email, Zelis, Paychex, and ADP, by (a) name; (b) function and/or use; (c) dates of use; (d) the Wound Pros entities and/or individuals involved or impacted; and (e) the name(s) and title(s) of the employees or other third parties most knowledgeable about its function and/or use.
- 6. For each system, program, platform, software, algorithm, analytic, or other tool identified in response to interrogatory 5, describe (a) all fields that are auto-populated by the system; (b) all fields that are added or revised by anyone other than the provider who directly treated the patient; and (c) the circumstances under which those fields are auto-populated, added, or revised. If this process changed during the Relevant Time Period, describe all changes during this time period.
- 7. Identify in Microsoft Excel format all DME suppliers used by any person or entity affiliated with Wound Pros by (a) full name; (b) current or last known business address, home address, and telephone number; (c) NPI, if applicable; (d) tax identification number, if applicable; (e) DME supplies ordered from that supplier; and (f) dates during which DME supplies were ordered from that supplier.
- 8. Identify in Microsoft Excel format all DME orders filled by Wound Pros for DME, including (a) the item or service furnished; (b) the patient (i) full name, (ii) date of birth, (iii) social security number, and (iv) Medicare Beneficiary Number or other federal health care program identifier; (c) the referring physician; and (d) the amount reimbursed.
- 9. Identify in Microsoft Excel format all Wound Pros facilities and medical offices where services were provided by any Wound Pros provider by (a) full name; (b) address; (c) the date range(s) during which services were provided at that facility or medical office; (d) all persons and entities that billed the federal healthcare programs for services performed at that facility or medical office, including the person's or entity's NPI and EIN; and (e) the services provided at that facility.
- 10. Identify in Microsoft Excel format all patients treated by a Wound Pros non-physician practitioner, including identifying the patient by (a) full name; (b) date of birth; (c) social security number; (d) date of first encounter with Wound Pros; (e) date of the most recent encounter with Wound Pros; (f) date on which the service was provided; (g) whether the patient was treated with a skin substitute; (h) date of the skin substitute service, if any; (i) address where the service was performed; (j) whether the patient was located at a facility of any kind when the patient received the service, and if so, the type of facility, name of the facility, and address of the facility; (k) name of the person who performed the service; (l) name of the supervising physician, if any; (m) health insurance plan; (n) whether the patient was diagnosed with any condition related to the services provided, and if so, any associated diagnosis, HCPCS, and CPT codes; (o) all follow-up treatments

- associated with the services provided; and (p) all documentation or other information considered in connection with the services provided.
- 11. Describe Your corporate structure during the Relevant Time Period from Your corporate parent(s) through any holding companies, limited liability corporations, affiliated corporations or entities, partnerships, or subsidiaries, including specifically identifying the owner(s) of each such entity and the fractional share of ownership. If the structure has changed during the Relevant Time Period, describe all changes to the structure during this time period.
- 12. Describe Your relationship with each of the following entities, including any ownership interest, financial relationship, and overlap in providers, services, or patients: (a) Wound Pros Washington; (b) Wound Pros Utah; (c) Wound Pros Louisiana; (d) Wound Pros Illinois; (e) Texas Wound Care Management; (f) PLS Podiatry Group; (g) Ohio Wound Care Specialists; (h) Ohio Wound Care Network; (i) DPMOTIKONRCA LLC; (j) Coast to Coast Podiatry; (l) Coast to Coast Foot Doctors, a Podiatry Corporation; (m) Coast to Coast DME; (n) Christopher A Otiko DPM; (o) Global Wound Care Medical Group; (p) American Wound Care Partners; (q) National Wound Care Associates; (r) Horizon Wound Care LLC; and (s) PLS Foot Doctors. If the relationship has changed during the Relevant Time Period, describe all changes during this time period.